REMARKS

Claims 22-34 are pending in the Application. Claim 34 has previously been withdrawn as non-elected subject matter in response to a restriction requirement.

The Applicants have amended the claims to better define the non-obvious nature of the invention. The Applicants have amended claim 22 to now recite that the ratio of neutral phospholipid: cholesterol: charged phospholipid is 9:5:1. This amendment to claim 22 now incorporates the language of claim 29. Claim 29 has therefore been cancelled.

The Applicants have also herein amended claim 22 to now claim a parenteral pharmaceutical composition. Support for the amendment to claim 22 may be found in the Specification on page 4 in lines 18 – 19.

Claim 24 has been amended to correct a typographical error.

The examiner has rejected claims 22-33 under 35 U.S.C. § 112 2nd paragraph as being indefinite. The Examiner has stated that the terms BD and BDBB are indefinite. The Applicants respectfully disagree with the Examiner and request that the rejection be withdrawn. The Applicants assert that one skilled in the art would be fully apprised of the scope of the invention, with respect to what constitutes an alpha interferon B/D hybrid, from a reading of the claims in conjunction with a reading of the Specification. A claim is not indefinite because it is hard to understand when viewed without the benefit of the Specification. S3 Inc. v. nVidia Corp., 259 F.3d 1364, 59 U.S.P.Q. 2d 1745 (Fed. Cir. 2001). The Applicants have provided, in the Specification, at least three references, EP No. 0331635 and EP No. 0205404, and US Pat. No. 4414150, which adequately describe and upon which the Applicants rely to enhance their description of the metes and bounds of what constitutes a B/D hybrid of alpha interferon. The Applicants have thus provided specific references identified in the Specification, to describe what is meant by B/D and BDBB hybrids. The additional reference, cited by the Examiner, which are not part of the Applicants' Specification, should not confound the concept of what comprises a B/D hybrid or BDBB hybrid as claimed in the present application. The Applicants believe that the Sabbadin A et al. (Dev. Comp. Immunol. 1998 Fall; 12(4):737-47) reference does not confound the Applicants description of a B/D and BDBB alpha interferon hybrid. The Applicants assert that an alpha interferon B/D hybrid is a term which is used to describe

segments of the coding region of plasmids which correspond to the B and D segments of alpha interferon. The Applicants rely on the aforementioned patents identified in the Specification to describe what is meant by B and D segments. A B/D hybrid can be comprised of various combinations of interposed B and D segments of alpha interferon as disclosed in the relied upon references cited in the Specification. Therefore, there are various types of B/D hybrids which can be incorporated into the composition of the invention. The term BDBB for example, as stated in claims 23, refers to a specific B/D hybrid of alpha interferon which is comprised of B and D segments which are, in order, B, D, B and B. Therefore, the Applicants respectfully assert that one of ordinary skill in the art would be able to determine the scope of the invention as claimed from a reading of the claims in light of the Specification. Thus, the Applicants request that the rejection under 35 U.S.C. § 112 2nd paragraph be withdrawn.

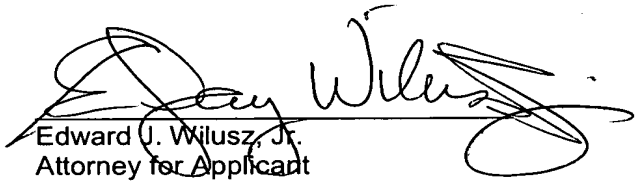
The Examiner has rejected claims 22-33 under 35 U.S.C. § 103(a) over Fidler et al (EP 0331635A2) in view of Weiner et al (WO 91/01719). The Examiner has stated that the addition of cholesterol to the Applicants' invention would have been appreciated by one of ordinary skill in the art. The Examiner provides the reference Yau-Young, A. (WO 87/0459) and indicates that Yau-Young teaches that the addition of cholesterol to a liposome increases its stability. The Applicants respectfully disagree with the Examiner's conclusions on the Yau-Young reference. Indeed, as cited by the Examiner, on page 8 in lines 21- 24, Yau-Young, states that "(i)n general cholesterol is known to increase liposome stability, and therefore might be expected to increase the time required for clearance of lipid and entrapped components...." However, Yau-Young proceeds to state on page 8 in lines 28-32 that cholesterol "...produced very little change in the rate of release of either lipid or encapsulated peptide from the site of injection." This last statement by Yau-Young in fact teaches away from the Applicants invention. At best, the statement by Yau-Young indicates that liposomal components must be evaluated on a case by case basis for their effects on the stability of unique liposomal compositions, such as that of the Applicants invention. One can not draw broad conclusions that cholesterol will produce the desired release characteristics such as acceptable release of liposome entrapped peptides after injection in to a subject. The Applicants have demonstrated that their invention does provide enhanced release characteristics and provide evidence of such acceptable enhanced release results as shown in Example 2 on page 6 of the Specification. Concerning the Examiner's comments about the Applicants previous arguments which indicate that the Applicants' claimed invention is directed to an injectable formulation, the Applicants believe that the current amendments render this part of the rejection moot. Therefore, based on the foregoing the Applicants respectfully request that the Examiner withdraw the rejection of claims 22-33 under 35 U.S.C. § 103(a) over Fidler et al (EP 0331635A2) in view of Weiner et al (WO 91/01719).

The Applicants believe that case in now in condition for allowance and respectfully request early notice to that effect.

The Examiner is herein authorized to charge Deposit Account No. 19-0134 in the name of Novartis Corporation for fees which may be properly assessable in the case and to refund fees paid in excess of amounts due.

If it will advance prosecution of the Application the Examiner is urged to contact the Applicants' undersigned counsel at the telephone number listed below.

Respectfully submitted,



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